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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,633	10/02/2003	Jeffrey C. Cerier	064391-5010-US	4181

43850 7590 01/15/2008
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EXAMINER	
WOO, JULIAN W	

ART UNIT	PAPER NUMBER
3773	

MAIL DATE	DELIVERY MODE
01/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/677,633	CERIER, JEFFREY C.
	Examiner	**Art Unit**
	Julian W. Woo	3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2007*.
2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-28 and 41-44* is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *7-28 and 41-44* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a)☐ All b)☐ Some * c)☐ None of:
1.☐ Certified copies of the priority documents have been received.
2.☐ Certified copies of the priority documents have been received in Application No. _____.
3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 11-13, and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Bonutti (6,592,609). Bonutti discloses, at least in figure 9 and in col. 15, line 64 to col. 16, line 52; a tissue fixation device including a looped suture (190) suitable for in vivo placement in a human or animal body, first and second, biocompatible, and rotatable securing elements (196, 188) respectively attached to first and second portions (192, 194) of the suture, where the securing elements are suitable to pass though holes formed in human or animal tissue and rotate from a first position to a second position that inhibits the securing element from passing through the holes; where the first and second securing elements are spaced apart from a third portion of the suture, and where a portion of the suture is coupled to another portion by welding (via "ultrasonic vibratory energy").

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 7-10, 42, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Merser (3,399,432) in view of Robbins (2,104,885). Merser discloses, at least in figures 1-8 and 11-13; the invention substantially as claimed. Merser discloses a tissue fixation device including first and second sutures (1, 1'), a first pledget (B") with first and second through holes (2'), first and second securing elements (3') each rotatable from a first orientation to a second orientation (see figs. 1-8, 10 and 11), and where first and second portions of each suture are respectively connected to first and second securing elements. However, Merser does not disclose a second pledget having at least one through hole. Robbins teaches, at least in figure 4 and in col. 2, line, 30 to col. 3, line 2; a fixation device with first and second pledgets (17, 18) connected with a suture and securing elements. It would have been obvious to one having ordinary skill in the art, in view of Robbins, to include a second pledget with the fixation device of Merser. Such a pledget or backing would protect fabric or tissue from chafing or ripping by first and second securing elements placed in contact with the

second pledget, and it would prevent the securing elements from being pulled through the holes in the relatively more pliant fabric or tissue. Also, Merser or Merser's combination with Robbins does not disclose that the sutures and the second securing element are suitable for in vivo suturing of human or animal tissue or comprise biocompatible material. Nevertheless, it would have been obvious to one having ordinary skill in the art to form the sutures and element out of biocompatible materials, since the fixation device is exposed to or in contact with human and/or animal bodies (e.g., when the device is being used with fabrics or garments for humans and animals). Moreover, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply biocompatible materials in the fixation device, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

5. Claims 11-14, 16, 17, and 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whaley (GB 2075829). Whaley discloses the invention substantially as claimed. Whaley discloses, at least in figures 1a, 1b, and 7; a tissue fixation device including a suture (1) and first and second securing elements (2, 3) respectively attached to first and second portions of the suture, where the first and second securing elements are spaced apart from a third portion of the suture, where a portion of the suture is coupled to another portion by knotting, where first and second portions of the suture are respectively passed through openings in the first and second securing elements, and where the suture is endless or forms a closed loop. However, Whaley

does not disclose that the suture and the first and second securing elements are suitable for in vivo placement in a human or animal body or are biocompatible. Nevertheless, it would have been obvious to one having ordinary skill in the art to form the suture and elements out of biocompatible materials, since the fixation device is exposed to or in contact with human and/or animal bodies (e.g., when the device is being used with upholstery for human and animal furniture). Moreover, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply biocompatible materials in the fixation device, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

6. Claims 11, 18, 20-24, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over La Torraca (3,900,925). La Torraca discloses the inventions substantially as claimed. La Torraca discloses, at least in figures 2-5, a tissue fixation device including a suture (22) and first and second securing elements (24) respectively attached to first and second portion of the suture, and a first pledget having a plurality of holes (27), where the suture passes through the holes, where the suture has two ends disposable on the same side of the pledget (see fig. 5), where the first and second securing elements are oriented at least substantially parallel to the holes in a first position (see fig. 3) and are at least substantially perpendicular to the holes in a second position (e.g., see fig. 5), where the first and second securing elements are generally cylindrical in shape or have an elongated shape, such that the long axis of a securing element is larger than the diameter of a hole in the pledget. However, La Torraca does

not disclose that the suture and the first and second securing elements are suitable for in vivo placement in a human or animal body or are biocompatible. Nevertheless, it would have been obvious to one having ordinary skill in the art to form the suture and elements out of biocompatible materials, since the fixation device is exposed to or in contact with human and/or animal bodies (e.g., when the device is being used with clothing fabrics for humans and animals). Moreover, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply biocompatible materials in the fixation device, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

7. Claims 11 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deschenes et al. (5,671,507). Deschenes et al. disclose, at least in figures 1-5 and in col. 5, lines 10-14; a tissue fixation device including a suture (e.g., 13) and first and second securing elements (e.g., 21, 23) respectively attached to first and second portion of the suture, and a deployment instrument (as disclosed in U.S. Patent No. 5,383, 260, incorporated by reference), where the first and second securing elements are rotatable from a first position to a second position (see fig. 2), and where the first and second securing elements (43, 45) each include a sharp tip (47, 49). However, Deschenes does not disclose that the suture and the first and second securing elements are suitable for in vivo placement in a human or animal body or are biocompatible. Nevertheless, it would have been obvious to one having ordinary skill in the art to form the suture and elements out of biocompatible materials, since the fixation

device is exposed to or in contact with human and/or animal bodies (e.g., when the device is being used with fabrics or garments for humans and animals). Moreover, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply biocompatible materials in the fixation device, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

8. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over La Torraca (3,900,925) in view of in view of Robbins (2,104,885). La Torraca discloses the invention substantially as claimed, but does not disclose a second pledget having a plurality of through holes. Robbins teaches, at least in figure 4 and in col. 2, line, 30 to col. 3, line 2; a fixation device with first and second pledgets (17, 18) connected with a suture and securing elements. It would have been obvious to one having ordinary skill in the art, in view of Robbins, to include a second pledget with the fixation device of La Torraca. Such a pledget or backing would protect fabric or tissue from chafing or ripping by first and second securing elements placed in contact with the second pledget, and it would prevent the securing elements from being pulled through the holes in the relatively more pliant fabric or tissue.

9. Claims 41 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deschenes et al. (5,671,507) in view of Robbins (2,104,885). Deschenes et al. disclose the invention substantially as claimed. Deschenes et al. disclose, at least in figures 2, 3, and 5 ; a tissue fixation device including a suture (13), first and second second securing elements (43, 45) with sharp tips (47, 49), and a first pledget (B) with a

plurality of through holes (B_1 and B_2). However, Deschenes et al. do not disclose a second pledget having a plurality of through holes. Robbins teaches, at least in figure 4 and in col. 2, line, 30 to col. 3, line 2; a fixation device with first and second pledgets (17, 18) connected with a suture and securing elements. It would have been obvious to one having ordinary skill in the art, in view of Robbins, to include a second pledget with the fixation device of Deschenes. Such a pledget or backing would protect fabric or tissue from chafing or ripping by first and second securing elements placed in contact with the second pledget, and it would prevent the securing elements from being pulled through the holes in the relatively more pliant fabric or tissue. Also, Deschenes et al. do not disclose that the second securing element comprises biocompatible material. Nevertheless, it would have been obvious to one having ordinary skill in the art to form the element out of biocompatible materials, since the fixation device is exposed to or in contact with human and/or animal bodies (e.g., when the device is being used with fabrics or garments for humans and animals). Moreover, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply biocompatible materials in the fixation device, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

Response to Amendment

10. Applicant's arguments with respect to claims 7-28 and 41-44 have been considered but are not fully persuasive in view of new and restated grounds of rejection.

With respect to arguments regarding the rejection of claims based on the references of Merser, Robbins, and Deschenes: The Applicant has stated that the references do not disclose a pledget. The Examiner respectfully disagrees. First of all, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed (in human or animal tissue in this case) does not differentiate the claimed apparatus from a prior art apparatus (e.g., buttons) satisfying the claimed structural limitations. The structure of the members or buttons in the references meets structural limitations of the claimed pledgets. Secondly, the members or buttons disclosed in the references, indeed, meet the definition of "pledget," as cited by the Applicant and when the term is given its broadest reasonable interpretation. That is, the members or buttons are "small, flat compress[es]...used to protect," where the members or buttons are usable to compress and protect portions of fabrics or garments.

The Applicant has also stated that combining the teachings of Robbins with the disclosure of Merser, would be "detrimental" to Mercer's device and method. On the contrary, the device and method taught by Robbins are within the same, analogous art of Merser, and Robbins indeed provides motivation and teachings for modifying Merser. That is, Robbins demonstrates the need for a "second button" (Applicant's description) along with a first button, and one of ordinary skill in the art would be motivated to modify Merser, so that fabric or even tissue would be further protected with another "button."

The Applicant has also argued that if a "second button" is applied with Deschenes's button, then a second button "would necessarily have holes" like the holes in Deschenes's button, and would "simply fall off" as soon as it is released from a fabric or garment. On the contrary, a second button having holes like the holes of Deschenes's button (B1 and B2) would not result in the second button falling. The holes in Deschenes's button are sized to receive the "feet" of the fixation device when they are in rotated positions aligning the longitudinal axes of the "feet" with the axes of the holes. Similarly, the holes in a second button would be sized to receive the "feet" and allow retention of the button to fabric or tissue when the "feet" are rotated to positions transverse to the axes of the holes. Also, the "feet" of Deschene's fixation device may also have sharp tips, which would allow easy penetration of fabric or tissue.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Julian W. Woo

Julian W. Woo
Primary Examiner

January 14, 2008